BK Medical

Convex Array Transducer

User Guide

Types 8567-S and 8667

English
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we specialize because you do

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Convex Array Transducer Types 8567-S and 8667

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Introduction

This is the user guide for Convex Array Transducer Types 8567-S and 8667 and must be used together with *Transducer Care, Cleaning & Safety* which contains important safety information.

8567-S and 8667 are suitable for prostate scanning and transvaginal examinations.

Fig. 1. Convex Array Transducer Types 8567-S and 8667

Scanning Plane

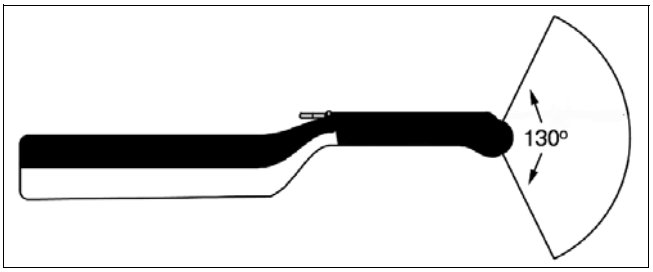

Fig. 2. Scanning plane of Types 8567-S and 8667

General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are on the Technical Data CD (BZ2100) that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

WARNING

If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:

- *Remove all transducers from contact with the patient.*
- *Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.*
- *Do not remove the scanner cover.*
- *Contact your B-K Medical representative or hospital technician.*

WARNING
Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Transducer Care, Cleaning & Safety.*

Cleaning and Disinfection

To ensure the best results when using B-K Medical equipment, it is important to maintain a strict regular cleaning routine.

Full details of cleaning and disinfection procedures can be found in the *Transducer Care, Cleaning & Safety* booklet that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more details.

WARNING
Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department or hospital.

Caution
Keep all plugs and sockets absolutely dry at all times.

Starting Scanning

All equipment must be cleaned and disinfected before use.

Connecting the Transducer

WARNING
Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the scanner using the array Transducer Socket on the scanner. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the scanner socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected the transducer complies with Type B requirements of EN60601-1 (IEC 60601-1).

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the scanning frequency. See the applicable scanner user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.

WARNING
Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply gel to the tip of the transducer. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

Gel also creates a good acoustic contact between the skin and the transducer; therefore, apply a small amount to the outside of the cover prior to scanning. Re-apply the gel frequently to ensure good screen images.

WARNING
Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.

Using the Transducer Control Button

The transducer has a control button that you can press to **Start** or **Stop** scanning (freeze frame). Press the button for more than one second to make a copy of the image.

Note: Transducer buttons cannot be used to copy images using the Mini Focus 1402 Ultrasound Scanner.

Each time the button is pressed, a “beep” is emitted.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable scanner user guide for instructions.

Transrectal Scanning

Smear a small amount of scanning gel over the tip of the transducer cover. This will ease insertion and improve the screen images.

WARNING

Do not use excessive force during insertion. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

Transvaginal Scanning with Ultrasound Scanner 1402

It is possible to scan transvaginally with Type 8667.

Note: Type 8667 is intended for transvaginal scanning only with the Ultrasound Scanner 1402.

Before transvaginal scanning, ensure the patient's bladder is empty.

Smear a small amount of scanning gel over the tip of the transducer cover. This will ease insertion and improve the screen images.

Puncture Facilities

Transrectal puncture and biopsy are possible with Types 8567-S and 8667. The puncture attachment is illustrated in the following pages with a brief description of its use and operating instructions.

WARNING

It is essential for the patient's safety that only the correct puncture attachment is used with Types 8567-S and 8667. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

Biopsy System

The biopsy system consists of:

- a metal puncture attachment UA1256 (item A in Fig. 3.) or single use plastic puncture attachment UA1256-U;
- a re-usable biopsy gun, for example a Bard® Magnum® biopsy gun (item B in Fig. 3.);
- 17 gauge biopsy needles for use with UA1256 or 18 gauge needles for use with UA1256-U.

The biopsy system shown in Fig. 3. is intended for transrectal puncture and biopsy only.

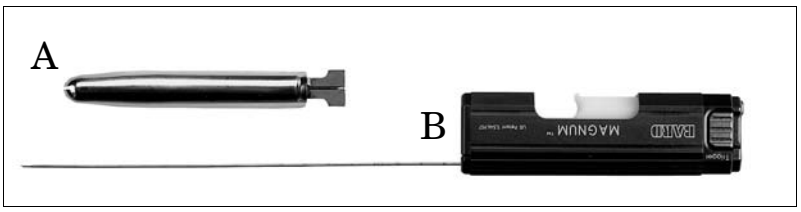

Fig. 3. The puncture attachment UA1256 and Bard® Magnum® biopsy gun

The puncture attachment UA1256 comprises a needle guide with an inner diameter of 1.5mm, suitable for up to 17 gauge needles. The single use puncture attachment UA1256-U comprises a needle guide with an inner diameter of 1.3mm, suitable for up to 18 gauge needles.

The needle guide is angled 0° towards the long axis of the transducer (i.e. towards the mid-axis of the scan image with Types 8567-S and 8667). The distance from the entrance to the needle guide and the first puncture line dot on the scan image is 126mm as shown in Fig. 6. The dots are 5mm apart.

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution.

Puncture attachment UA1256-U is supplied sterile and is for single use only.

WARNING

Cover the transducer with a sterile transducer cover before mounting the puncture attachment.

To mount the puncture attachment, position it over the transducer and click into place (see Fig. 4.).

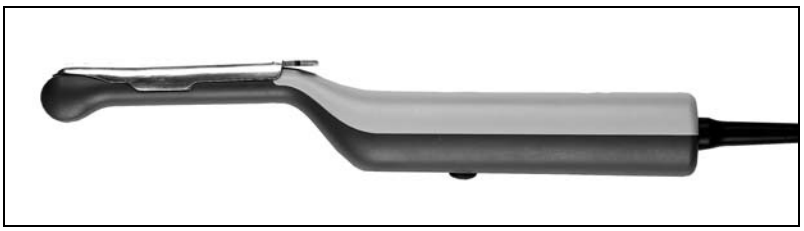

Fig. 4. Type 8567-S / 8667 with puncture attachment UA1256

Caution:

Ensure the puncture attachment is securely in place and the tip of the needle guide lies close to the front end of the probe. If not, the needle guide may be damaged and require realignment by B-K Medical technicians.

To attach the biopsy gun:

1. Hold the transducer with the puncture attachment uppermost.

2. Position the biopsy gun on the puncture attachment as shown in Fig. 5..

Fig. 5. Type 8567-S / 8667 with puncture attachment UA1256 and Bard® Magnum® biopsy gun in place

The biopsy gun featured is a Bard® Magnum® reusable biopsy gun, which is an optional accessory with Transducer Types 8567-S and 8667. Other biopsy guns can also be used with UA1256 and UA1256-U.

If using another biopsy gun, ensure that it can use needles with a minimum length of 16cm. Consult your local B-K Medical representative for further information.

WARNING
Before performing a biopsy, please refer to the user manual supplied with the biopsy gun.

Performing Puncture and Biopsy

Transrectal Biopsy

WARNING
It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the scanner monitor.

WARNING
The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

Cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

See the Product Data sheet for a list of available transducer covers.

Press the scanner **Puncture** or **Biopsy** control button to superimpose a puncture line on the scan image.

If more than one puncture line is available, refer to the applicable scanner user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

WARNING
If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

To remove the puncture line from the scan image, refer to the applicable scanner user guide for instructions.

WARNING
When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

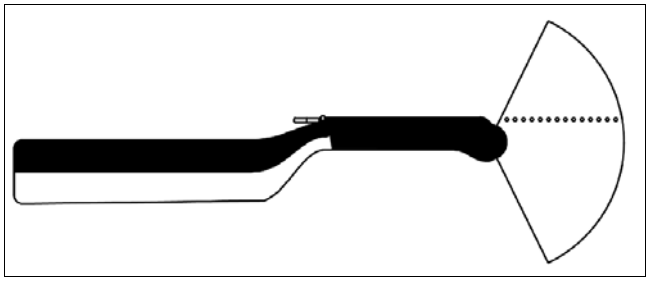

Fig. 6. Illustration of the puncture line for puncture attachment UA1256

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or puncture attachments, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture attachments and transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Transducer Care, Cleaning & Safety* for cleaning instructions.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable scanner user guide for further details.

WARNING
For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.